UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 5, 2022

ALDEYRA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	001-36332	20-1968197
(State or other jurisdiction of incorporation)	(Commission File No.)	(IRS Employer Identification No.)

131 Hartwell Avenue, Suite 320
Lexington, MA 02421
(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALDX**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On August 5, 2022, Aldeyra Therapeutics, Inc. (“Aldeyra” or the “Company”) issued a press release (the “Press Release”) and is holding a conference call regarding its financial results for the quarter ended June 30, 2022 and recent corporate highlights. The Press Release (other than the sections incorporated by reference pursuant to Item 8.01) is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the timing of planned NDA submissions; the anticipated timing of enrollment and results from Aldeyra’s clinical trials; expectations regarding the results of scheduled and planned pre-NDA meetings, including the FDA’s acceptance of Aldeyra’s post-hoc review of data, the FDA’s agreement with Aldeyra’s methods of analyzing data and the FDA’s agreement that data from the crossover clinical trial can be used to support the safety or efficacy of reproxalap; and Aldeyra’s projected cash runway. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as, but not limited to, “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “anticipate,” “project,” “on track,” “scheduled,” “target,” “design,” “estimate,” “predict,” “potential,” “aim,” “plan” or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation, enrollment or completion of clinical trials. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, and endpoints acceptable to applicable regulatory authorities; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity, or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates in clinical trials focused on the same or on different indications; the risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra’s ability to commercialize (alone or with others) and obtain reimbursement for Aldeyra's product candidates following regulatory approval, if any; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; political, economic, legal, social, and health risks, including the COVID-19 pandemic and subsequent public health measures, and war or other military actions, that may affect Aldeyra’s business or the global economy; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra’s limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra’s ability to successfully integrate acquisitions into its business; Aldeyra's expectations regarding federal, state, and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2021, and Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/. Additional factors may be set forth in those sections of Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, expected to be filed with the SEC in the third quarter of 2022. In addition to the risks described above and in Aldeyra’s other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra’s results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information conveyed on the conference call is provided only as of the date of the call, and Aldeyra undertakes no obligation to update any forward-looking statements presented on the call on account of new information, future events, or otherwise, except as required by law.

The information in Item 2.02 of this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

In the Press Release dated August 5, 2022, the Company also provided a corporate update. The information set forth under the headings "Recent Corporate Highlights" and "Upcoming Planned Clinical and Regulatory Milestones," together with the "Safe Harbor Statement" at the end of the Press Release, are incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

The portions of the Press Release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to Item 8.01. The remaining portions of the Press Release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated August 5, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALDEYRA THERAPEUTICS, INC.

By: /s/ Todd C. Brady

Name: Todd C. Brady, M.D., Ph.D.
Title: Chief Executive Officer

Dated August 5, 2022

Exhibit 99.1

Aldeyra Therapeutics Reports Second-Quarter 2022 Financial Results and Recent Corporate Highlights

- ***Pre-NDA (New Drug Application) Meeting with the U.S. Food and Drug Administration (FDA) Scheduled for the Third Quarter of 2022 to Discuss NDA Submission of Reproxalap for the Treatment of Dry Eye Disease***
- ***Pre-NDA Meeting with the FDA Planned for the Second Half of 2022 to Discuss NDA Submission of ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma***
- ***Top-line Results from Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy Expected in the Second Half of 2022***
- ***Top-line Results from Phase 2 Clinical Trial of Oral RASP Modulator ADX-629 in Acute Alcoholic Hepatitis Expected in the Second Half of 2022***
- ***Cash, Cash Equivalents, and Marketable Securities of $196.7 Million as of June 30, 2022***
- ***Management to Host Conference Call at 8:00 a.m. ET Today***

LEXINGTON, Mass.--(BUSINESS WIRE)--August 5, 2022--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases, today reported recent corporate highlights and financial results for the quarter ended June 30, 2022.

“The second half of 2022 is highlighted by planned new drug applications in dry eye disease and primary vitreoretinal lymphoma, two diseases that are currently sub-optimally treated,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “In addition, we look forward to announcing the results of the Phase 3 GUARD trial of ADX-2191 in proliferative vitreoretinopathy later this year, as well as the Phase 2 results of the oral RASP modulator ADX-629 in a challenge model of acute alcoholic hepatitis.”

Recent Corporate Highlights

- **Positive Results from the Dry Eye Disease Chamber Crossover Clinical Trial:** Reproxalap was statistically superior to vehicle for each of the two prespecified primary endpoints, ocular redness in a dry eye chamber (P=0.0004) and Schirmer test (P=0.0005), a measure of tear production, after a single day of dosing. The secondary endpoint of Schirmer test ≥10 mm responder analysis, which was multiplicity-controlled and has been reported to correlate with symptomatic improvement in dry eye disease,[1] was also achieved (P=0.0361). Rapid and statistically significant reductions in patient-reported ocular discomfort and dryness were observed in the dry eye disease chamber.
- **Positive Results from the Phase 3 TRANQUILITY-2 Trial in Dry Eye Disease:** Reproxalap was statistically superior to vehicle for each of the two prespecified primary endpoints, Schirmer test (P=0.0001) and Schirmer test ≥10 mm responder analysis (P<0.0001) after a single day of dosing.

Upcoming Planned Clinical and Regulatory Milestones

- **NDA Submission of Reproxalap in Dry Eye Disease:** Pending discussions with the FDA and enrollment in the 12-month safety trial of reproxalap in patients with dry eye disease, Aldeyra intends to submit an NDA with data on ocular dryness symptom score, ocular redness, Schirmer test, and Schirmer test ≥10 mm responder analysis, encompassing results across five adequate and well-controlled completed clinical trials. A pre-NDA meeting with the FDA to discuss the regulatory package has been scheduled for the third quarter of 2022.
- **Pre-NDA Meeting for ADX-2191 in Primary Vitreoretinal Lymphoma:** Aldeyra plans to conduct a pre-NDA meeting with the FDA in the second half of 2022 to discuss ADX-2191 for the treatment of primary vitreoretinal lymphoma. Pending discussion with the FDA, an NDA submission is planned for the second half of 2022.
- **Results from the Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy:** Top-line results from Part 1 of the Phase 3 GUARD trial of ADX-2191 in patients with proliferative vitreoretinopathy are expected in the second half of 2022.
- **Results from the Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa:** Top-line results from the Phase 2 clinical trial of ADX-2191 in patients with retinitis pigmentosa are expected in the first half of 2023.
- **Results from Phase 2 Clinical Trials of ADX-629 in Systemic Immune-Mediated Diseases:** In the second half of this year, Aldeyra expects to report top-line results from a Phase 2 clinical trial in acute alcoholic hepatitis, and to initiate Phase 2 clinical trials in Sjögren-Larsson Syndrome and minimal change disease. Top-line results from the ongoing Phase 2 clinical trial of ADX-629 in chronic cough are anticipated in the first half of 2023.

Second-Quarter 2022 Financial Results

Cash, cash equivalents, and marketable securities as of June 30, 2022 were $196.7 million. Based on its current operating plan, Aldeyra believes that existing cash, cash equivalents, and marketable securities will be sufficient to fund currently projected operating expenses through the end of 2023, including planned NDA submissions and initial commercialization of reproxalap and ADX-2191, if approved, and continued development of Aldeyra's product candidates in ocular and systemic immune-mediated diseases.

Net loss for the three months ended June 30, 2022 was $17.8 million, or $0.30 per share, compared with a net loss of $14.9 million, or $0.28 per share, for the comparable period of 2021. Losses have resulted from the costs of clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses for the three months ended June 30, 2022 were $14.6 million, compared with $11.5 million for the same period in 2021. The increase of $3.1 million is primarily related to increases in external clinical and preclinical development costs, and drug product manufacturing expenditures.

General and administrative expenses for the three months ended June 30, 2022 were $3.1 million, compared with $3.1 million for the same period in 2021.

Total operating expenses for the three months ended June 30, 2022 were $17.7 million, compared with total operating expenses of $14.5 million for the same period in 2021.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss recent corporate highlights and financial results for the quarter ended June 30, 2022. The dial-in numbers are (844) 200-6205 for domestic callers and (929) 526-1599 for international callers. The access code is **908644**. Please dial in at least 10 minutes prior to the start time.

A live webcast of the conference call can be accessed via the Investors & Media page of the Aldeyra website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the website for 90 days.

About Aldeyra

Aldeyra is a clinical-stage biotechnology company developing innovative therapies designed to treat immune-mediated diseases. Our approach is to discover pharmaceuticals that modulate immunological systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Two of our lead product candidates, reproxalap and ADX-629, target pre-cytokine, systems-based mediators of inflammation known as RASP (reactive aldehyde species). Reproxalap is in late-stage clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 clinical testing for the treatment of systemic immune-mediated diseases. Our pipeline also includes ADX-2191 (intravitreal methotrexate 0.8%), in development for the prevention of proliferative vitreoretinopathy and the treatment of retinitis pigmentosa and primary vitreoretinal lymphoma. For more information, visit https://www.aldeyra.com/ and follow us on LinkedIn, Facebook, and Twitter.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the timing of planned NDA submissions; the anticipated timing of enrollment and results from Aldeyra's clinical trials; expectations regarding the results of scheduled and planned pre-NDA meetings, including the FDA's acceptance of Aldeyra's post-hoc review of data, the FDA's agreement with Aldeyra's methods of analyzing data and the FDA's agreement that data from the crossover clinical trial can be used to support the safety or efficacy of reproxalap; and Aldeyra's projected cash runway. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. 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Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; updated or refined data based on Aldeyra's continuing or post-hoc review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols, data analysis methodologies, and endpoints acceptable to applicable regulatory authorities; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity, or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates in clinical trials focused on the same or on different indications; the risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra's ability to commercialize (alone or with others) and obtain reimbursement for Aldeyra's product candidates following regulatory approval, if any; the size and growth of the potential markets and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; political, economic, legal, social, and health risks, including the COVID-19 pandemic and subsequent public health measures, and war or other military actions, that may affect Aldeyra's business or the global economy; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's ability to successfully integrate acquisitions into its business; Aldeyra's expectations regarding federal, state, and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2021, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://www.sec.gov/. Additional factors may be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, expected to be filed with the SEC in the third quarter of 2022.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

[1] Schiffman RM, Christianson MD, Jacobsen G, Hirsch JD, Reis BL. Reliability and validity of the Ocular Surface Disease Index. Arch Ophthalmol. 2000;118(5):615-21.

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	June 30, 2022	December 31, 2021
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 42,012,015	$ 104,790,989
Cash equivalent - reverse repurchase agreements	79,000,000	125,000,000
Marketable securities	75,677,040	—
Prepaid expenses and other current assets	4,052,355	2,961,781
Total current assets	200,741,410	232,752,770
Right-of-use assets	239,873	351,863
Fixed assets, net	34,041	32,487
Total assets	$ 201,015,324	$ 233,137,120
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 264,225	$ 1,019,702
Accrued expenses	10,810,155	10,523,353
Current portion of long-term debt	4,925,765	—
Current portion of operating lease liabilities	242,636	229,607
Total current liabilities	16,242,781	11,772,662
Operating lease liabilities, long-term	—	125,232
Long-term debt, net of current portion	10,743,535	15,503,703
Total liabilities	26,986,316	27,401,597
Stockholders' equity:		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding	—	—
Common stock, voting, $0.001 par value; 150,000,000 authorized and 58,301,491 and 58,081,215 shares issued and outstanding, respectively	58,301	58,081
Additional paid-in capital	503,517,715	500,369,444
Accumulated other comprehensive loss	(285,763)	—
Accumulated deficit	(329,261,245)	(294,692,002)
Total stockholders' equity	174,029,008	205,735,523
Total liabilities and stockholders' equity	$ 201,015,324	$ 233,137,120

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 14,570,654	$ 11,474,446	$ 26,804,975	$ 19,200,788
General and administrative	3,144,280	3,068,652	7,393,667	6,173,355
Loss from operations	(17,714,934)	(14,543,098)	(34,198,642)	(25,374,143)
Other income (expense):				
Interest income	344,378	39,665	445,760	63,427
Interest expense	(410,395)	(433,477)	(816,361)	(916,056)
Total other income (expense), net	(66,017)	(393,812)	(370,601)	(852,629)
Net loss	$ (17,780,951)	$ (14,936,910)	$(34,569,243)	$(26,226,772)
Net loss per share - basic and diluted	$ (0.30)	$ (0.28)	$ (0.59)	$ (0.52)
Weighted average common shares outstanding - basic and diluted	58,301,491	54,280,393	58,299,686	49,979,545

Contacts

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